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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/119,209

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EXAMINER

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ART UNIT

PAPER NUMBER

1646

DATE MAILED:

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/119,209Applicant(s)
Laskey et al.Examiner
Michael PakArt Unit
1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 30, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-56 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed 30 July 2001 (Paper No. 15) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 10 October 2000 (Paper No. 13) have been fully considered but they are not found persuasive.

Terminal Disclaimer

4. The complete copy of the terminal disclaimer filed on 5 October 2000 has been received. The terminal disclaimer filed on 5 October 2000 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,216,131 and 5,840,844 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 49 and 51-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 49 and 51-53 recite or encompass the term "hybridize under stringent conditions" which is a relative term and the metes and bounds of the term is not clear.

Claims 49-56 recite or encompass the term "carbohydrate binding domain", "epidermal growth factor domain", and/or "complement binding domain" which is confusing because it is not clear what is the metes and bounds of the domains structurally.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 49-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention.
This a written description rejection.

Claims 49-53 encompass fragments and variants of LHR without functional limitation. Claims 54-56 encompass fragments of specific domains which are not clearly delineated and without functional limitation. However, the essential feature of the invention is the specific LHR of SEQ ID NO:2 with specific function, and one of skilled in the art cannot envision the full genus of molecules of the claimed variants and fragments without functional limitation. Claimed nucleic acid encoding protein variants encompass a large genus of ion channels which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring receptor is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

Claim Rejections - 35 USC § 102

9. Claims 49-51 and 54-56 remains rejected under 35 U.S.C. 102(b) as being anticipated by Woodruff et al. ((39); Ann. Rev. Immunol., 1987).

The reasons for the rejection has been set forth in the

previous office action.

Applicants argue that the specification teaches the process of isolating the claimed protein using monoclonal while the Woodruff et al. used polyclonal antibody which results in a myriad of different isolated polypeptide. However, the claims are generic structurally and encompass comprising other polypeptides because the term "isolated" does not exclude other proteins. Since the protein is isolated in the Woodruff preparation and it is isolated from the same cell, the protein inherently has the same structure.

Applicants argue that Woodruff does not disclose the structural sequence. However, the protein is the same and the sequence is inherent to the protein.

Woodruff et al. disclose the human lymphocyte homing receptor (pages 216-218)

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Jalkanen et al. (IDS references 17-20) are cumulative reference with Woodruff et al. ((39); Ann. Rev. Immunol., 1987). Applicants cite Bowen et al. which teach that comparison of Hermes sequence with the human pln receptor reveal no significant sequence homology. However, the generic claims are not directed to specific species of SEQ ID NO:2 and thus encompass the

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proteins of Jalkanen et al.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
16 October 2001